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RESPONSE TO OFFICE ACTION

This communication is being filed in response to the Office Action dated February 6, 2006.

Petition for an Extension of Time

Applicants petition for an extension of two months for filing this response. The Office is hereby authorized to debit the official fee, and any additional fees that may fall due, from deposit account number 50-1230 (Martin A. Hay & Co).

Elections/Restriction

The Examiner has requested that the present application be restricted under 35 U.S.C. § 121 to one of four inventions, identified as Groups I, II, III and IV in the Office Action.

Applicants hereby affirm their provisional election of Group I, claims 1-14 and 17.

From the Examiner's reference to the rejoinder procedures set forth in M.P.E.P. § 821.04, it is understood that the Examiner will consider rejoining all of the withdrawn claims upon determining that the invention of Group I, Claims 1-14 and 17 is patentable.

Claim Rejections - 35 U.S.C. § 112

The Examiner has rejected Claims 2-5 and 12-14 as allegedly failing to comply with the requirements of 35 U.S.C. § 112, first paragraph. It is understood that the Examiner is concerned that levalbuterol L-tartrate might be capable of existing in a crystalline form that the present specification does not teach.

It is respectfully submitted that Claims 2-5 and 12-14 do comply with the requirements of 35 U.S.C. § 112, first paragraph. Applicants have taught how to make and use the compound as claimed. There is no reason in law why the protection granted for a novel compound invention should not extend to that compound in any form, including forms yet to be discovered.

When drafting applications directed to the protection of novel compounds, it is conventional to include claims directed to specific embodiments of the invention that find practical application, such as methods of use, processes for making the compounds and pharmaceutical compositions containing them. In the case of the present application, it is levalbuterol L-tartrate in crystalline form that finds practical application - it enables levalbuterol to be delivered into the lungs of patients using a metered dose inhaler.

Quite possibly there are inventions yet to be made concerning new methods of use of levalbuterol L-tartrate, new processes for making levalbuterol L-tartrate, new pharmaceutical compositions of levalbuterol L-tartrate and indeed new crystalline forms of levalbuterol L-tartrate. However, exploitation of each of these hypothetical inventions would not be possible without Applicants' original invention of the compound.

The Examiner has also rejected Claims 2-5 under 35 U.S.C. § 112, second paragraph. The Examiner asserts that "compounds" and "compositions" constitute distinct classes of inventions, and that Claims 2-5 cannot satisfy the requirements of 35 U.S.C. § 112, second paragraph because they cannot be classified with Claim 1 as compound claims.

It is respectfully submitted that Claims 2-5 satisfy the requirements of 35 U.S.C. § 112, second paragraph.

Applicants' invention is a novel compound, levalbuterol L-tartrate. This is the subject of all of Claims 1 to 5, not levalbuterol L-tartrate and some other substance.

Claim 1 is directed to levalbuterol L-tartrate as a novel compound. The claim reads on levalbuterol L-tartrate in any form, including any crystalline form, alone (pure) or in combination with any amount of any other substance or substances. When in combination with another substance, the levalbuterol L-tartrate may be in the form of crystals also containing another substance and/or mixed with another substance.

Claims 2 to 5 are directed to levalbuterol L-tartrate when in a particular form. The scope of the claims is clear. A person skilled in the art would have no difficulty in determining whether or not a given product contains levalbuterol L-tartrate in the defined form.

In real life, it is impossible to obtain a chemical substance in a form totally free of other substances. Pharmacists often use the term "residual substances" to denote the impurities that remain in a drug after purification. Any real product containing levalbuterol L-tartrate will in fact contain levalbuterol L-tartrate in a form that is a combination of levalbuterol L-tartrate and some other substance or substances.

Very occasionally, a patentable invention can arise which concerns a substance in a form defined by the residual substances it contains, or does not contain. An example of such an invention is claimed in US 5,470,865. The Examiner is kindly referred to the claims in that patent.

Claim Rejections - 35 U.S.C. § 103

Claims 1-14 and 17 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over WO 2002/78671. Claims 1 and 2 also stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over CN 1382685.

WO 2002/78671 was published on October 10, 2002 and CN 1382685 on December 4, 2002.

Applicants in fact had possession of the claimed invention before October 10, 2002 and indeed had conducted clinical trials in the United States before this date. Details of these clinical trials were provided to the Examiner in a supplementary information disclosure statement received by the office on December 3, 2004.

Applicants submit herewith a Declaration under Rule 131 affirming that they had possession of the invention before the publication dates of WO 2002/78671 and CN 1382685. Unfortunately, due to the Holidays, the Applicants are not available to sign this document at this time. A signed declaration will be provided as soon as possible.

The present invention provides a salt of levalbuterol that affords crystals capable of delivering levalbuterol into the lungs of a patient using a metered dose inhaler.

At the time that the present invention was made, the only known salt of levalbuterol (to the best of Applicants' knowledge) was the hydrochloride, which was disclosed in US 5,545,745. As described in the introduction to the present specification, crystals of levalbuterol hydrochloride had been found to possess properties undesirable in a product intended for administration using a metered dose inhaler.

As the Examiner has stated, crystalline form is

highly unpredictable. Knowledge of the properties of salts of other compounds, such as albuterol, would not have assisted a person skilled in the art in his search for a salt of levalbuterol that affords crystals suitable for formulation in a metered dose inhaler.

It is therefore respectfully submitted that the presently claimed invention would not have been obvious to a person skilled in the art.

Conclusion

Applicants respectfully submit that the present application is in order to receive a Notice of Allowance.

Communication by Telephone

The undersigned's office is located in the United Kingdom, and hence the Examiner may have difficulty contacting him from the USPTO by telephone. If the Examiner wishes to speak with the undersigned by telephone, the undersigned can be contacted by e-mail at martinahay@martin-a-hay.com and will call the Examiner as soon as possible.

Respectfully submitted,

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